

Enzymatic Therapy

NATURAL MEDICINES®

January 21, 2004

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pure Core™	Dietary Supplement for sustainable support of overall good health*	Vitamin A (as natural beta carotene with mixed carotenoids), Vitamin C (ascorbic acid), Vitamin E (as d-alpha tocopheryl succinate), Thiamin (as thiamin hydrochloride), Riboflavin (as riboflavin 25 mg, riboflavin-5'- phosphate 10mg), Niacin (as niacinamide, Niacinol®), Vitamin B 6 (as pyridoxine HCl 50mg, pyridoxal-5'-phosphate 10 mg), Folic Acid, Vitamin B 12 (as cyanocobalamin), Biotin, Panthothenic Acid (as calcium pantothenate), Calcium (as calcium lysinate, aspartate, citrate), Magnesium (as magnesium aspartate, citrate, glycinate, lysinate), Zinc (as zinc picolinate, lysinate, aspartate, glycinate), Selenium (as selenium aspartate, glycinate, lysinate complexes), Copper (as copper citrate, aspartate, glycinate, lysinate), Manganese (as manganese aspartate, lysinate, citrate, glycinate), Chromium (as chromium glycinate, aspartate,

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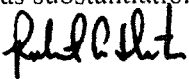
13647

825 Challenger Drive
Green Bay, WI 54311-8328
Ph: 920-469-1313
Fax: 888-570-6460
www.enzy.com

Pure Core 1c

		lysinate), Molybdenum (as molybdenum aspartate, glycinate, lysinate), Potassium (as potassium chloride), Choline (as choline bitartrate), Inositol, Vanadium (as vanadium aspartate, glycinate, lysinate)
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I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

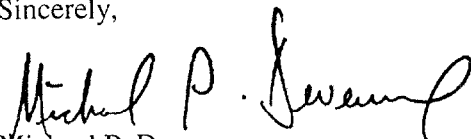
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/21/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer

Enzymatic Therapy

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pure Core™	Pure Core (Multiplex), for sustainable support of overall good health,* provides a full range of vital nutrients for the daily energy and essential nutrition that every active person needs.*	Vitamin A (as natural beta carotene with mixed carotenoids), Vitamin C (ascorbic acid), Vitamin E (as d-alpha tocopheryl succinate), Thiamin (as thiamin hydrochloride), Riboflavin (as riboflavin 25 mg, riboflavin-5'-phosphate 10mg), Niacin (as niacinamide, Niacinol®), Vitamin B 6 (as pyridoxine HCl 50mg, pyridoxal-5'-phosphate 10 mg), Folic Acid, Vitamin B 12 (as cyanocobalamin), Biotin, Panthothenic Acid (as calcium pantothenate), Calcium (as calcium lysinate, aspartate, citrate), Magnesium (as magnesium aspartate, citrate, glycinate, lysinate), Zinc (as zinc picolinate, lysinate, aspartate, glycinate), Selenium (as selenium aspartate, glycinate, lysinate complexes), Copper (as copper citrate, aspartate, glycinate, lysinate), Manganese (as manganese aspartate, lysinate, citrate, glycinate), Chromium (as chromium glycinate, aspartate,

		lysinate), Molybdenum (as molybdenum aspartate, glycinate, lysinate), Potassium (as potassium chloride), Choline (as choline bitartrate), Inositol, Vanadium (as vanadium aspartate, glycinate, lysinate)
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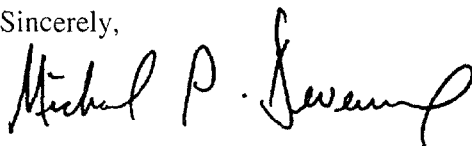
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